ing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e)(2)—the *Citrovit* was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and 502(f)—The labeling of the *Aspi-Quinine* and the *Giuliani Bitter Laxative* failed to bear (1) adequate directions for use and (2) (*Aspi-Quinine*) adequate warnings for the protection of the user and (*Giuliani Bitter Laxative*) a warning statement for phenolphthalein; 502(a)—when shipped and while held for sale, the labeling of the *Gastro-Zyme*, namely, the leaflet entitled "Gastro-Zyme I.S.M.," contained false and misleading representations that the article was an adequate and effective treatment for chronic (atrophic) gastritis; gastric achylia; dyspepsia in anemic convalescent and aged subjects, infants and over-worked people; gastric neuroses; senile gastric hypotonia and hypochylia; and acute and chronic gastric catarrh.

DISPOSITION: 3–1–60. Consent—claimed by Italian Drugs Importing Co., Inc., New York, N.Y., and relabeled.

6173. Desitin Rectal Ointment. (F.D.C. No. 44227. S. No. 67–957 P.)

QUANTITY: 60 individually cartoned tubes at Philadelphia, Pa.

SHIPPED: 12–23–59, from Providence, R.I., by Desitin Chemical Co.

LABEL IN PART: (Ctn. and tube) "1½ Ounces Rectal Desitin Ointment Contains: Zinc Oxide, Norwegian Cod Liver Oil, Lanolin, Talcum, Sodium Lauryl Sulfate, Petrolatum qs. Manufactured by Desitin Chemical Company Providence, R.I."

ACCOMPANYING LABELING: Leaflet in carton entitled "Why New Rectal Desitin Ointment is a superior therapy."

LIBELED: 2–10–60, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for hemorrhoids (internal and external), anorectal conditions; pruritus ani; fissures; cryptitis; papillitis; proctitis; perianal dermatitis; and wounds resulting from cryptectomy; proctotomy; fissurectomy; and fistulectomy; and 502(f)(2)—the labeling of the article failed to warn that in case of rectal bleeding a physician should be consulted immediately.

DISPOSITION: 3–9–60. Default—destruction.

6174. Niagara Cyclo-Massage devices. (F.D.C. No. 43175. S. No. 16–283 P.)

QUANTITY: 1 glide-out sofa, 2 chaise lounges, 6 thermopads, 22 hand units, 7 all-purpose cushions, 2 #100 provincial chairs, 1 #200 queen chair, 3 #300 king chairs, 3 #400 standard chairs, 1 foam rubber mattress, 1 3-way professional table, 2 executive cushions, 22 sets consisting of thermopads and hand units, at Indianapolis, Ind., in possession of Niagara Distributors, Inc., and Kittle's Niagara Dealers, Inc.

SHIPPED: Between January 1956 and 4–28–59, from Adamsville, Pa.

LIBELED: 6–22–59, S. Dist. Ind.

CHARGE: 502(f)(1)—while held for sale, the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of Buerger's disease, wrinkles, crow's feet and bagginess under the chin, skin cancer, cerebral palsy in children, nerve interference, flushing out toxic poisons in the bloostream, arthritis, bursitis, sinus attacks, high blood pressure, constipation, defective eyesight and hearing, paralysis and blindness

caused by multiple sclerosis, hemorrhoids, asthma attacks, heartburn, allergies, earache, sore throat, corns and callouses on feet, pimples, cancerous conditions, and reducing and gaining weight, which were the purposes for which the articles were offered orally by Lillian Acker, a saleslady on the dealer's premises.

DISPOSITION: 1-9-60. Default—1 all-purpose cushion, 1 #300 king chair, 5 sets consisting of thermopads and hand units, and 1 hand unit were ordered delivered to the Food and Drug Administration; 2 chaise lounges, 2 #100 provincial chairs, 2 #300 king chairs, 2 #400 standard chairs, and 1 foam rubber mattress were ordered delivered to a charitable institution for use as ordinary furniture after first removing and destroying the control unit in each device so as to render it inoperable for heat or vibrating purposes. The remainder of the articles were destroyed.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6175. Various drugs. (Inj. No. 350.)

COMPLAINT FOR INJUNCTION FILED: 1-23-59, N. Dist. Ill., against Hallmark Laboratories, Inc., a corporation, Custom Chemical Laboratories, a partnership, John Korabik, president of the corporation, Chicago, Ill., and Otto K. Benca, treasurer of the corporation and partner in the partnership, Cicero, Ill.

CHARGE: The complaint alleged that the defendants were engaged in manufacturing, preparing, packing, labeling, selling, and introducing and delivering for introduction into interstate commerce, various drugs which were adulterated and misbranded as follows:

501(b)—a number of such drugs purported to be drugs the names of which are recognized in the United States Pharmacopeia and the strength of the drugs differed from, or their quality or purity fell below, the standards set forth in such compendium;

501(c)—the strength of a number of such drugs differed from, or their quality fell below, that which they purported and were represented to possess;

502(a)—the labeling of a number of such drugs bore false and misleading statements with respect to the nature and quantity of the ingredients contained in the drugs;

502(e)(2)—a number of such drugs were not designated solely by a name recognized in an official compendium, were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient; and

502(g)—a number of such drugs purported to be drugs the names of which are recognized in the United States Pharmacopeia and they were not labeled as prescribed by such compendium.

It was alleged also that the defendants were causing to be introduced and delivered for introduction into interstate commerce, contrary to the provisions of Section 505(a), new drugs which did not have effective new drug applications on file.

It was alleged further that, in the manufacturing, packaging, selling and distribution of the drugs, essentially the following methods were used:

(a) Hallmark Laboratories, Inc., purchased raw materials from various sources and furnished them to Custom Chemical Laboratories; (b)

Custom Chemical Laboratories manufactured bulk solutions of drugs for parenteral injection from said raw materials without making assays either of said raw materials or the prepared bulk solutions made from said raw materials; and

(c) the defendants then caused the bulk solutions to be transported to another manufacturer who repackaged the bulk solutions into either 10- or 30-cc. vials; that said 10- or 30-cc. vials were then returned to the premises of Hallmark Laboratories, Inc., where they were labeled and stored and from where they were distributed in interstate commerce.

The complaint alleged further that the adulterated and misbranded condition of said drugs resulted from deficiencies in the ingredients of the drugs; the presence in the drugs of ingredients in amounts in excess of those declared on the labels; the presence in the drugs of ingredients other than given on the labels; or the presence in the drugs of foreign matter, due either to inadequate manufacturing facilities, lack of identification control, lack of adequate analyses and formulas, lack of qualified personnel, or lack of other precautions essential to the compounding of potent drugs. For example, the 10-cc. vials of *Dexalamine ampuls* contained methapyrilene hydrochloride instead of pyranisamine maleate the ingredient given on the label, and contained racemic amphetamine in the amount of 3.7 milligrams rather than 2 milligrams of dextro-amphetamine sulfate; the *Solution of Vitamin* B_{12} (*Cyanocobalamin U.S.P.*) vials, the *Vitamin* B_{12} (*Cyanocobalamin U.S.P.*) *In Water For Injection* vials, and the vials of *Vitamin* B_{12} *Crystalline U.S.P. 1000 Micrograms per cc. in Isotonic Sod. Chloride Soln. with 2% Benzyl Alcohol* all contained a substantial amount of unidentified dissolved material not permitted by the United States Pharmacopoeia monograph for *cyanocobalamin injection;* the 30-cc. vials of *Water For Injection U.S.P.* contained ½ percent of phenol, an added preservative, and its label failed to reveal that fact and the amount present as required in the United States Pharmacopoeia monograph for *Water For Injection;* the *Liver Injection U.S.P.* (Beef) contained more than 50 percent of the amount of cyanocobalamin shown on the label; the vials of *Sterile Progesterone U.S.P.* contained viable microorganisms and were not sterile; the *B-Complex with Vitamin* B_{12} contained approximately 140 percent of the declared amount of riboflavin and was approximately 66 percent deficient in vitamin B_{12}; and the *Liver-Folic Acid-*B_{12} was approximately 66 percent deficient in vitamin B_{12}.

It was alleged further that defendants were well aware that their activities violated the Act; that inspections were made of Hallmark Laboratories, Inc., in 1957 and 1958, and of Custom Chemical Laboratories in 1957, at which times the defendants were informed of the inadequacies encountered; that defendants were further warned by seizures of their vitamin B_{12} for injection, and by hearings pursuant to Section 305 of the Act; and that despite such warnings, the defendants continued to introduce and cause to be introduced and deliver and cause to be delivered for introduction into interstate commerce, adulterated and misbranded drugs.

DISPOSITION: On 2–6–59, the defendants having consented, a temporary injunction was entered. The temporary injunction was subsequently extended by consent and on 2–15–60, at which time it was revised, it was extended until 2–15–62. The revised temporary injunction enjoined and restrained the defendants from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce, drugs such as those named above or any similar drugs that are

adulterated or misbranded as alleged in the complaint or are new drugs which do not have an effective new drug application on file.

The temporary injunction further enjoined the defendants from directly or indirectly causing to be introduced or delivered for introduction into interstate commerce, any drug manufactured, processed, relabeled, or repacked by them unless and until:

(a) Sufficient qualified and experienced personnel, including supervisory personnel are employed in the plant to properly operate it;

(b) A properly qualified pharmaceutical chemist is employed to make sufficient analyses of each batch of finished drug to insure that it conforms to the labeling under which it is to be shipped, and to the requirements of the National Formulary or United States Pharmacopoeia or other standard which may be applicable. Lacking this, a representative sample of each finished batch of drugs is submitted to a reliable established outside laboratory for examination and the results of such examination are received prior to shipment;

(c) A system of properly identifying and storing raw materials as they are received at the plant is instituted;

(d) Batches of drugs in preparation are not manipulated in an improper manner resulting in unwarranted shortages or overages in the final yield;

(e) Sampling of finished tablets, injectionables, and all other finished products is done in a representative manner to insure the taking of a representative, adequate sample;

(f) Capsules are assayed in finished form rather than in earlier stages of manufacture;

(g) The practice of shipping finished batches of drugs prior to analysis or without analysis is discontinued;

(h) The distribution of new drugs without effective new drug applications is discontinued;

(i) At least one qualified person in the plant has sufficient information concerning the new drugs shipped from this plant to eliminate confusions and violations;

(j) Adequate samples of incoming raw materials are taken and appropriate analyses of these samples made;

(k) Preparation of manufacturing records and forms is done with such clarity, care and completeness that each lot or batch of drugs manufactured, processed, relabeled, or repacked is so identified that the complete manufacturing, packing, and labeling history and control examination reports are readily available and so as to eliminate mistakes and confusion;

(l) Each batch or lot of drugs manufactured, processed, relabeled or repacked is properly identified at all times and during all stages of said manufacturing, processing, relabeling, or repacking;

(m) Operations involving the weighing out of raw materials and the preparation of formulas and application of labeling are checked by another qualified party in addition to the employee originally performing such duties;

(n) Returned goods are recorded, handled, stored, and again disposed of in a manner which will eliminate uncertainty, confusion, and the possibility of mistakes;

(o) Samples of each lot of raw materials and each batch or lot of drugs manufactured, processed, relabeled, or repacked by them are taken and

retained for the time reasonably necessary for the distribution and use of drugs distributed; and

(p) Representatives of the Food and Drug Administration of the Department of Health, Education, and Welfare are given free access to all records and controls pertaining to (1) the receipt of all raw materials or lots of drugs for manufacturing, processing, repacking, or relabeling; (2) the manufacturing, processing, repacking, or relabeling of all lots or batches of drugs; and (3) the distribution of all batches or lots of drugs whether interstate or intrastate, including, but not limited to, the records necessary to establish that adequate control systems have been installed embodying all of the herein listed safeguards for interstate commerce considered necessary to good pharmaceutical manufacturing practice.

6176. Conjugated estrogen powder. (F.D.C. No. 43181. S. No. 11-062 P.)

QUANTITY: 8 cans, each containing 2 kilograms, at Buffalo, N.Y.

SHIPPED: 5-2-58, from Montreal, Canada, by Steroid Laboratories, Ltd.

LABEL IN PART: "Product of Steroid Laboratories Limited Box 247 Montreal Canada 2 kilograms Conjugated Estrogens (Equine) Powder Each Gram Contains 17.1 Mg. Estrogens (as Conjugates)—Control No. 91497."

RESULTS OF INVESTIGATION: Analysis showed that total estrogen content corresponded to not more than 14.7 mgs. of estrone per gram.

LIBELED: 6-6-59, W. Dist. N.Y.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each gram contains 17.1 Mg. Estrogens" was false and misleading since the article contained not more than 14.7 mg. of estrone per gram.

DISPOSITION: 2-8-60. Consent—claimed by Steroid Laboratories, Ltd., and relabeled.

6177. Conjugated estrogen granules. (F.D.C. No. 44054. S. No. 86-566 P.)

QUANTITY: 4 cans containing a total of about 6,176 grams of estrogen (equine) granules at Buffalo, N.Y.

SHIPPED: 9-1-59, from Brooklyn, N.Y., by International Hormones, Inc., after having been imported during 1956, from Steroid Laboratories, Ltd., Montreal, Canada.

LABEL IN PART: (Can) "International Hormones, Inc. * * * Brooklyn 1, N.Y. 1546 Grams Conjugated Estrogens (Equine) Granules 7.074 mg/gram Estrogens after Hydrolysis * * * Control #79001."

RESULTS OF INVESTIGATION: Analysis showed the total estrogen content corresponded to not more than 4.61 mgs. of estrone per gram.

LIBELED: 2-4-60, W. Dist. N.Y.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "7.074 mg/gram" was false and misleading as applied to an article which contained 4.61 mgs. of estrone per gram.

DISPOSITION: 3-9-60. Default—destruction.